

b.) Remarks

Claims 98 and 113 have been amended, and claim 119 added, in order to more specifically recite various preferred embodiments of the present invention. The subject matter of the amendment may be found throughout the specification as filed, including page 6, lines 27-30. Accordingly, no new matter has been added.

Claims 98, 102-105 and 108-118 are rejected under 35 U.S.C. §112, first paragraph, as failing to comply with the written description. According to the Examiner there is no disclosure of the term “milk” in the specification as filed. In response, Applicants wish to clarify that the terms “WPI 97” and “WPC 80” at specification page 5, lines 4-5 are respectively powdered and granulated milk whey products as shown on their attached product information sheets.¹ Use of whey protein isolate is also illustrated in the present invention at page 12, line 24.

In that regard, to complete the record, those persons skilled in the art in any event are well-aware that soy proteins are conventionally characterized as “SPI” (e.g., soy protein isolate). In contrast, whey products are conventionally characterized by “WPC” or “WPI” (e.g., whey protein concentrate and whey protein isolate, respectively). Therefore “whey” and “soy” have definitive and sufficiently distinct meanings in the art such that reference to “WPI”, for example, is readily understood as necessarily referring to dairy protein. Accordingly, this rejection is overcome.

Claims 98, 102-105 and 108 stand rejected under 35 U.S.C. §103(a) as being obvious over Tabor (US Pat. 6,482,448) in view of Hastings (US 2001/0041187), Miller

¹ The WPI 97 sheet explains that powdered Whey Protein Isolate is produced by separating the cord portion of milk fat, filtering the watery liquid portion to remove lactose and ash, removing whey by cross flow microfiltration and drying the whey. Similarly, granulated WPC 80 is “manufactured from sweet dairy whey.” See Exhibits A and B attached to the Declaration noted at footnote 2.

(US Pat 6,019,999), Ostlund (US Pat 5,550,166) and Shimizu (US Pat 6,004,926), in further view of Goldberg et al (*Med. Sports Sci.*, Vol. 7, No. 3 (1975) 185-98) and Goldberg (*Diabetes*, Vol. 28, Supp. 1 (1979) 18-24).

This rejection is respectfully traversed. Prior to setting forth their bases for traversal, however, Applicants would briefly like to discuss the salient features of the present invention and *inter alia* its patentable nature over the prior art.

As the Examiner is well-aware, the present invention most broadly relates to a method for supplementing a human diet for enhancing muscle size or strength by orally administering (i) milk whey protein or milk whey peptide powder or granules, (ii) myo-inositol, d-myo-inositol, cis-inositol, epi-inositol, allo-inositol, muco-inositol, neo-inositol, scyllo-inositol, d-chiro-inositol, l-chiro-inositol or d-pinitol, and (iii) an ingredient that increases nitric oxide production.

None of the cited art teaches or suggests the subject matter of the present invention, as discussed below.

- Tabor U.S. Patent No. 6,482,448 is entitled “Soy Formulations and their Use for Promoting Health”. Tabor does not mention milk protein.

- Hastings U.S. 2001/0041187 teaches a powder supplement in which the major ingredient is soy protein (Paragraphs 0006, 0007)” as acknowledged by the Examiner. Hastings does not mention milk protein.

- Miller U.S. Patent No. 6,019,999 is cited by the Examiner as showing a “liposome, ion-exchange whey protein” at column 7, lines 46-60. Applicants’ claims, however, are directed towards powders or granular milk whey protein and peptides, not to liposome preparations. Additionally, Miller does not teach or suggest combining whey

with “a compound which mimics or enhances insulin activity... and at least one ingredient which increases nitric oxide production” as recited in claim 98 of the instant application.

- Ostlund U.S. Patent No. 5,550,166 is relied on as showing nutritional compositions containing pinitol for treating metabolic disorders. Aside from the deficiencies discussed above, enhancing muscle size and strength is not a “metabolic disorder.”

- Shimizu U.S. Patent No. 6,004,926 teaches something called “soy whey”. Applicants previously discussed this terminology is meaningless to those of skill in the art and cited to three dictionaries in support of the same. Although the Examiner disagreed² such concern is off-point; Shimizu nevertheless does not teach or suggest Applicants milk whey protein and peptides.

- Lastly, the Goldberg reference merely relates to the use of insulin for reducing protein breakdown in skeletal muscle.

In view of the above amendments and remarks, Applicants submit that all of the Examiner's concerns are now overcome and the claims are now in allowable condition. Accordingly, reconsideration and allowance of this application is earnestly solicited.

Claims 98, 102-105 and 108-119 remain presented for continued prosecution.

² The Examiner noted copies of the dictionary citations were not provided. To complete the record they are attached hereto, together with a Declaration of Ken Clement.

Applicants' undersigned attorney may be reached in our New York office by telephone at (212) 218-2100. All correspondence should continue to be directed to our below listed address.

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